Assumptions and uncertainties - Statement on the safety of Titanium Dioxide (E171) as a Food Additive

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Evidence base

289. This risk assessment is to assess the safety of TiO_2 E171 as a food additive. There were a few well conducted studies which allowed reasonable conclusions to be drawn. However, during the assessment of the scientific evidence it was noted that the TiO_2 used in the studies was not always well characterised, which can make it difficult to confirm what the effects are for specific forms of TiO_2. Some studies had used food grade TiO_2 or specifically E171. However, for other studies it was less certain what the form of TiO_2 was due to poor characterisation or TiO_2 engineered NPs had been used. These do not have the same characteristics as food grade TiO_2 and would not be used for this purpose. It was therefore uncertain how relevant toxicity data from these studies were to E171 or food grade TiO_2.

290. Another aspect of the dosing regimen was whether the TiO_2 had been sonicated to reduce/remove particle agglomeration. It was uncertain whether the toxicity profile of these would be the same as that of TiO_2 when used as a food

additive.

291. A significant number of studies did not use a dietary feeding route for dosing and the relevance of data from those studies, for the assessment of TiO_2 as a food additive, was uncertain. Some studies used drinking water or gavage and potentially the TiO_2 would not have the same physicochemical characteristics or toxicokinetics as when combined with the diet and consumed.

Exposure assessment

292. The exposure assessment takes into account use levels in only sixteen food groups, whereas E171 is approved in more categories (forty-eight). This may introduce underestimations for exposures. However, not all foods within the categories assessed will contain E171, which means exposure in those categories may be overestimated. In addition, the assessments are based on the assumption that all food in these categories contain E171 at the maximum reported levels. It is very unlikely that all foods in every category assessed will contain E171 and that this will be at the maximum reported levels. This assumption may overestimate exposure.

293. There are differences between the granularity of food groups used by EFSA for the purposes of their exposure assessment, and those used here for the UK population. This could introduce uncertainties about the comparability of the data.

294. The European Union (EU) banned the use of titanium dioxide as a food additive in 2022. This followed EFSA's update on the safety of the food additive and taking into account uncertainties around genotoxicity concerns (Commission Regulation (EU) 2022/63). Titanium dioxide has not been banned in the UK. However, the EU ban on titanium dioxide may lead to a decline in its use by industry, even for foods consumed in the UK. For these reasons, the exposure estimates derived may overestimate current and future exposure to titanium dioxide in the UK population.

295. The exposure estimates do not account for exposures from medicines, toothpaste and other non-food sources. Exposure may be higher if these other sources are taken into account.